

Genome editing: Legal expert criticises opinion of Attorney General of the EuCJ

No clear distinction between breeding and genetic engineering
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On 18 January, the Attorney General of the EU Court of Justice (EuCJ) published his position on whether or not so-called genome editing must be regulated under current EU GMO legislation. On behalf of Testbiotech, the well-known EU legal expert Professor Ludwig Kraemer has now analysed the position of the Attorney General (C-528/16). Professor Kraemer worked as an official for the EU Commission (DG Environment) until 2004 and was involved in drawing up the current EU GMO regulations. In his legal dossier, published today, Professor Kraemer gives several reasons for criticising the position of the Attorney General.

According to Professor Kraemer, there is no doubt that the new methods of genetic engineering must be regulated under the current EU Directive 2001/18. At the time that the EU directive was drawn up, the only methods of plant and animal breeding exempted from GMO regulation were those which were considered to "have a long safety record". This is, however, not the case with the new techniques of genetic engineering, which make use of tools such as CRISPR/ Cas. Consequently, plants and animals that are gene-edited should undergo an approval process and risk assessment before they can be allowed for release or import. Nevertheless, the Attorney General has not made a clear distinction between genetic engineering and conventional breeding.

Furthermore, as Professor Kraemer points out, the Attorney General's interpretation of the precautionary principle is flawed. If there are uncertainties in regard to the safety of organisms in the context of new techniques of genetic engineering, the regulation requires investigation of these risks. These rules have to be applied at EU level and cannot – contrary to the opinion of the Attorney General – be left to up to individual EU member state regulation.

Major loopholes in EU GMO regulation might emerge if the EU Court of Justice follows the opinion of the Attorney General. If this is the case, Testbiotech demands that political decision-makers must take action to, for example, prevent uncontrolled imports or releases of genetically engineered organisms into the environment.

Testbiotech emphasises that the assessment of the new methods of genetic engineering is not only a question of legalities. From a biological point of view, the risks and processes of genome editing are different from those of conventional breeding, even if no genes are transferred across the species. To explain these differences, Testbiotech is today publishing two short briefings on the differences between CRISPR/Cas and conventional breeding using mutagenesis.

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Further information: [Legal dossier drawn up by Professor Ludwig Kraemer](#) [2]

[Briefings on CRISPR/Cas and Mutagenesis](#) [3]

[The statement of the Attorney General](#) [4]

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